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Title: Effect of baseline eosinophil count on response to CYT003-QbG10 in patients with persistent allergic asthma

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Body: Background The novel TLR-9 agonist CYT003-QbG10 (CYT003) has clinical activity in persistent allergic asthma thought to be mediated via inhibition of TH2 immune response. Aims This post-hoc analysis of a proof-of-concept randomised phase IIa study in mild-to-moderate controlled asthma tested the effect of CYT003 vs placebo on treatment response markers by TH2 status assessed by baseline blood eosinophil count (bEos). Methods 63 patients received 7 doses of CYT003 (n=33) or placebo (n=30) over 12 weeks, with controlled ICS withdrawal in the last 8 weeks. Findings were stratified by an approximate median split of bEos. Results Mean (SE) bEos were 0.087 (0.01) in the lower (≤0.1 cells/nL) and 0.310 (0.03) in the higher bEos group. In higher bEos, ACQ increased significantly (p=0.002) from baseline with placebo (n=17) compared with CYT003 (n=16). This effect was evident before ICS withdrawal but was more obvious after (figure). There was no significant ACQ difference in patients with lower bEos (n=13 [placebo] and n=17 [CYT003]). FeNO (p=0.041) and FEV_1 deteriorated significantly with placebo compared with CYT003 (p=0.006) in patients with higher, but not lower, bEos. Conclusions Efficacy of CYT003 was most obvious in patients with evidence of TH2 activation. The effect persisted during ICS withdrawal, consistent with an inhibitory effect on TH2 immune responses. These findings warrant further investigation.